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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,459	10/02/2001	Fernando DiCaprio	S63.2-10083	9616

490 7590 12/03/2004

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MINNETONKA, MN 55343-9185

EXAMINER

HO, UYEN T

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/970,459

Applicant(s)

DICAPRIO ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, and 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shull et al. (6,143,022) in view of Savin et al. (4,950,227). Shull et al. disclose a stent (9) may be made from self expanding material (col. 8, lines 48-50) and a membrane (20) disposed about the stent wherein the membrane is made from PTFE or polyurethane and has a thickness between .001 and .003 inches (col. 6, lines 44-55). Although, Shull et al. fail to disclose a catheter having sleeves for delivering the stent, attention is directed to the Savin et al. reference which discloses a stent delivering system including sleeves for securing and maintaining a reduced diameter of self expanding stent on a balloon (figs. 1-7) for delivering to a deployment site. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a delivering system having sleeves for delivering the self-expanding stent of Shull et al. in order to secure the stent to a delivery catheter and maintain its reduced diameter configuration during delivery of the stent.

In regard to claim 8 and 12, it is known in the art to employ drug into/onto a membrane covering a stent or making a stent cover including water-soluble drug in order to deliver drug to a treated site. Therefore, it would have been obvious to one

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having ordinary skill in the art at the time the invention was made to employ drug into/onto a membrane covering Shull's stent in order to provide a local treatment at a treated site.

3. Claims 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herweck et al. (6,270,523) in view of Savin et al. (4,950,227). Herweck et al. disclose a stent as claimed (5A-5B). Although, Herweck et al. fail to disclose a catheter having sleeves for delivering the stent, attention is directed to the Savin et al. reference which discloses a stent delivering system including sleeves for securing and maintaining a reduced diameter of self expanding stent on a balloon (figs. 1-7) for delivering to a deployment site. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a delivering system having sleeves for delivering the self-expanding stent of Herweck et al. in order to secure the stent to a delivery catheter and maintain its reduced diameter configuration during delivery of the stent.

### ***Response to Arguments***

4. Applicant's arguments filed 6/17/04 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion or motivation to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one

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of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the obviousness is established as the Savin et al. teaching the knowledge generally available to one of ordinary skill in the art to use a sleeve for delivering the self-expanding stent. Therefore, in order to deliver the self expanded stent of Shull, one ordinary skill in the art would look for means to deliver the self expanded stent and Savin et al. reference teaches a sleeve to keep the self-expanding stent in a low profile for delivering to a desired site. The motivation for combining The Shull and Savin et al. <sup>as</sup> is indicated in the rejection above that <sup>is</sup> to hold the self-expanding stent and to secure the stent to a delivery catheter and maintain its reduced diameter configuration during delivery of the stent. Doing so would meet all the claim limitation. Since the sleeve <sup>is</sup> holding the stent in reduced diameter configuration, it inherently prevents the stent from flaring during delivering procedure.

### **Conclusion**

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

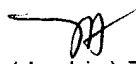
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
(Jackie) Tan-Uyen T. Ho  
Patent Examiner  
Art Unit 3731

November 19, 2004

  
ANHTUAN T. NGUYEN  
PRIMARY EXAMINER

11/24/04